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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/642,522

08/15/2003

Joseph P. Errico

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10/02/2008

SPINE MP

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

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DELIVERY MODE

10/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/642,522	<b>Applicant(s)</b> ERRICO ET AL.	
	<b>Examiner</b> Brian E. Pellegrino	<b>Art Unit</b> 3738	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 July 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 and 11-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/21/08 has been entered.

### ***Priority***

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 120, is acknowledged. However, Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: no petition was filed with the late claim for priority.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the *first sentence(s) of the specification* following the title or in an application data sheet during the proper time frame. For benefit claims under 35 U.S.C. 120, the reference must include the proper relationship (i.e., continuation, divisional, or continuation-in-part) of the applications desired to claim priority during the permitted time frame for submitting the claim to priority.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and *within the later of four months from the actual filing date of the application* or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). *A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c).* The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition

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should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4,8,9,21-24,26-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Ralph et al. (2003/14112). The invention as claimed is fully disclosed See Figs. 1.2, 1.4, 1.6, 1.7, 5.5 and paragraphs 18,19,89,90,94,118,122.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner (5370697) in view of Hedman et al. (4759769). Fig. 5 shows a vertebral contact element **44** having a resting shape of a dome convexly extending from an orthopedic device **2**. It is noted that in both Figs. 1a,5 the mesh is shown with a gap or space to result in the central region being remote from the baseplate surface. Clearly the gap is evident since the baseplate is not illustrated as being domed. Baumgartner discloses the contact element is a wire mesh (col. 3, lines 54-57) that is porous. The mesh is fully capable of having a convexity depth or footprint approximating and engaging the depth of a concave surface in vertebrae. However, Baumgartner fails to disclose the outer surface having a groove or an osteoconductive feature, such as a coating adjacent the contact element. Hedman et al. teach (Figs. 1,2) that a recess or groove **34,52** is used in the plate surfaces to secure or retain the resilient spring

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elements therein. Hedman also teaches that a coating for osteoconductive purposes is placed on the baseplate surfaces, col. 4, lines 4-9. It would have been obvious to one of ordinary skill in the art to utilize a groove to retain a compressible member therein as taught by Hedman et al. with the implant of Baumgartner such that it provides a more secure fastening of the mesh to the implant surface and eliminates any sliding or dislodgement of the mesh from the baseplates. In addition it would have been obvious to one of ordinary skill in the art to incorporate a coating as taught by Hedman with the vertebral implant of Baumgartner such that it provides a means to bond the surface with the vertebrae.

Claims 11-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baumgartner '697 in view of Krebs et al. '685 and in view of Hedman et al. '769. Baumgartner and Hedman et al. are explained above. It can also be seen (Fig. 1a) that the Baumgartner prosthesis is designed for some movement. Baumgartner does disclose materials that permit movement, col. 3, lines 19,20, 31. It can also be seen (Fig. 5) that the central region is remote from the outward surface of the baseplate and only perimeter areas that engage the baseplate. However, Baumgartner fails to disclose the outer surface groove and a coating to secure the outer convex contact vertebral member. Krebs et al. teach that a coating or binder is used to secure a metal mesh to the surface of the implant, col. 2, lines 14,17,36-39. It would have been obvious to one of ordinary skill in the art to incorporate a groove in the surface of the plate as taught by Hedman with the spinal implant of Baumgartner having the outer mesh and to further use a coating to secure the mesh as taught by Krebs such

that it prevents the contact element from sliding along the surface of the baseplates or being dislodged from the surface.

### ***Response to Arguments***

Applicant's arguments filed 7/21/08 have been fully considered but they are not persuasive. Applicants argue that the Baumgartner mesh disposed on the outer surface of a baseplate does not have a gap or is remote from the groove incorporated therein to the central portion of the mesh. Applicants allege that "cross-hatching" illustrates the central portion to not be remote or have a gap to space the central portion of the mesh from the central location of the baseplate. The Examiner respectfully disagrees since the "cross-hatching" is clearly different than that of the mesh and thus it cannot be said that it is the mesh that exists between the baseplate central region to the mesh's central area because of some alleged "cross-hatching". The disclosure of Baumgartner provides no recitation to support Applicants conclusion. Thus, Applicants' argument is unpersuasive. Applicant then argues that the teaching references of Krebs and Hedman both also fail to teach a gap or space to result in the central portion of the mesh to be remote from the baseplate. First it should be noted the references were used to provide teachings for modifying the baseplate of Baumgartner to better accommodate the mesh disclosed by Baumgartner. The Examiner never suggested any modification to the mesh of Baumgartner only to suggest modifying the baseplate outer surface such that within the outer surface a recess is incorporated for the mesh or spring element per the teaching of Hedman and the secure the mesh already on its surface using the teaching of Krebs to secure the contacting points of the mesh with the outer surface area using a



binder. Therefore, Baumgartner's domed mesh has a gap between its central region and the outer surface of the baseplate, Applicants then speculate that the perimeter of the mesh of Baumgartner cannot be placed in a groove stating it is flared to improve contact by the mesh and bone. However, Baumgartner never states anything about the perimeter so Applicants comments are mere speculation that its perimeter is flared for the purpose stated by Applicants.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738